

Amendments to the Drawings:

The attached sheets of drawings include changes to Figs. 1A, 1B, and 2. These sheets, which include Figs. 1A, 1B, and 2, replace the original sheets including Figs. 1A, 1B, 2 and 3.

Attachments: Replacement Sheets

REMARKS/ARGUMENTS

Amendments in General

1. Grammatical correction made in claim 1.
2. Claim 2 has been canceled.
3. The content from claim 2 has been amended to be contained in claim 1.
4. Due to the canceling of claim 2, claim 3 has been amended to be depended upon claim 1.
5. Grammatical correction made in claim 9.
6. Claim 10 has been canceled.
7. The content from claim 10 has been amended to be contained in claim 9.
8. Previous claim 10 limitations referring to an “ampule propellant chamber” have been removed and not included as content in claim 9.

Drawings

The Examiner did not accept the drawings received for the reason that the reference numbers “16” and “34” have both been used to designate the same end of the ampule as a “handle portion” and an “aperture”. Reference number 34 previously designated both the end portion and the handle portion in Figs. 1A, 1B, and Fig. 2.

The drawings in Fig. 1A and 1B have been amended to more accurately demonstrate the location of the handle portion in which reference number 34 directs to. This was accomplished by moving reference number 34 to a more accurate region. Also amended is reference number 52 indicating the end portion. Since reference number 34 was moved to indicate the handle portion, reference number 52 was included to designate the end portion.

The drawings in Fig 1A and 1B have been amended to include reference number 52 which properly indicates the end portion of the ampule. The drawing in Fig. 2 has been amended

by replacing reference number 52 for reference number 34, thus properly designating the end portion of the ampule in Fig. 2.

For the foregoing reasons, the Applicant respectfully requests acceptance of the drawings as amended. In response to the Examiner's rejections, the drawings have been amended as specified above. None of the amendments adds new matter.

Specification Amendments

The Examiner did not accept the drawings received for the reason that the reference numbers "16" and "34" have both been used to designate the same end of the ampule as a "handle portion" and an "aperture". Paragraph [0021] was amended to include the "end portion" to be designated by reference number 52 as to reflect the amendment to Fig. 1A, 1B, and Fig. 2.

All referenced items are previously referenced in paragraph [0021], the amendments refer to only the modification of reference numbers, and therefore none of the amendments adds new matter.

Claim Rejections – 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 10 and 11 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention for the following two reasons.

First, the Examiner noted that claim 10 and 11 were indefinite and failed to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Second, the Examiner noted that claim 10 recited "said propellant chamber" in line 2 and stated that it there is insufficient antecedent basis for this limitation in the claim.

With the content of claim 10 moved into claim 9 and the limitation "said propellant chamber" being removed from claim 10 in line 2, claim 9 now contains sufficient antecedent for all limitations in the claim. Subsequently, claim 10 and 11 now distinctly claim applicable subject matter.

For the foregoing reasons, the Applicant respectfully submits that claims 10 and 11, in light of the amendments to claim 9 and 10, comply with 35 U.S.C. § 112, second paragraph.

Claim Rejections – 35 U.S.C. § 102

“An applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. It is the Commissioner’s duty (acting through the examining officials) to determine that all requirements of the Patent Act are met. The burden is on the Commissioner to establish that the applicant is not entitled under the law to a patent . . . In rejecting an application, factual determinations by the PTO must be based on a preponderance of the evidence, and legal conclusions must be correct.” *In re Oetiker*, 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447, 24 USPQ2d at 1447 (Fed. Cir. 1992) (Plager, J., concurring). Further, “[t]he precise language of 35 USC 102 that ‘a person shall be entitled to a patent unless,’ concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103.” *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057, reh’g denied, 390 U.S. 1000 (1968).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 828 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). MPEP § 2131.

“The precise language of 35 USC 102 that ‘a person shall be entitled to a patent unless,’ concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103.” *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057, reh’g denied, 390 U.S. 1000 (1968).

Claims 1, 2, 3, 9, 10, and 11

The Examiner rejected claims 1, 2, 3, 9, 10, and 11 under 35 U.S.C. § 102(b) as being anticipated by the container for preserving medicaments described in U.S. Patent Number 2,787,269 (the Cohen patent).

Cohen describes a container for dental restoration material in which a plunger that is engaged with a cylindrical portion is used to push dental restoration material out through a nozzle. However, because the plunger is used to dispense the dental restoration material, Cohen does not teach or suggest an oral liquid medication dispensing system in which the medication is

expelled through a calibrated aperture, by the user manually providing lateral compression without the aid of external tooling. To the contrary, the plunger of the Cohen device is required at the time of dispensing to push out the material being dispensed from the Cohen “container.”

The container by Cohen does not teach or suggest the inclusion of an expelling material within the container. The ampule of the present application contains an amount of expelling material, preferably air, to provide a locomotive aid to the compound stored within the capsule. This is in stark contrast to the plunger required to move the material in the Cohen container. Further, the inclusion of the expelling material from the current invention would render the Cohen device inoperable. The expelling material would provide a restive force on the plunger of the Cohen device opposite direction of intention, resulting in either pushing the plunger completely out or moving the plunger a distance proportional to the force of pressure contained in the cylinder.

Cohen describes a container for dental restoration material in which the material stored inside said container is a binary compound used to form a settable paste when mixed together. Cohen does not teach or suggest an ampule configured to hold a premeasured quantity of selected medication.

Accordingly, the Applicant respectfully contends that Cohen does not anticipate claims 1, 2, 3, 9, 10, or 11.

Claims 1 and 2

The Examiner rejected claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by capsule puncturing device described in U.S. Patent Number 4,457,427 (the Cafiero patent).

Cafiero describes a puncturing device for medication containing capsules. Cafiero does not teach or suggest a capsule designed to the delivery of a premeasured amount of medication containing a plurality of medical compounds for oral consumption, or a design to separate said compounds inside the capsule during a period of storage. To the contrary, the Cafiero device suggests a solution to puncture the capsule to reduce the dose of a singular uncompounded substance.

The puncturing device as described by Cafiero does not teach or suggest the inclusion of an expelling material within the capsule. The ampule of the present application contains an amount of expelling material, preferably air, to provide a locomotive aid to the compound stored within the capsule.

The inclusion of an expelling material, the ability to store multiple materials, and the ability to combine multiple materials within the same capsule into a compound prior to consumption bring the present application significantly apart from the Cafiero device. Accordingly, the Applicant respectfully contends that, Cafiero does not anticipate claims 1 or 2.

Claim Rejections - 35 U.S.C. § 103

The Examiner rejected claims 6-8 and 14-16 under 35 U.S.C. § 103(a) as being unpatentable over the container for preserving medicaments described in U.S. 2,787,269 to Cohen in view of the capsule puncturing device described in U.S. 4,457,427 to Cafiero.

I. Prima Facie Obviousness

In order to sustain a rejection of the claims under §103(a), an examiner must initially put forth his/her prima facie case of obviousness. The Federal Circuit has made it clear that:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure.

In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 706.02(j).

Neither the Cohen container, nor the capsule puncturing device described by Cafiero teach or suggest the inclusion of an expelling material within the capsule or container. The ampule of the present application contains an amount of expelling material, preferably air, to provide a locomotive aid to the compound stored within the capsule.

Further, the inclusion of the expelling material from the current invention would render the Cohen device inoperable. The expelling material would provide a restive force on the plunger of the Cohen device opposite direction of intention, resulting in either pushing the plunger

completely out or moving the plunger a distance proportional to the force of pressure contained in the cylinder.

It does not follow that it would have been obvious to one with ordinary skill in the art to combine these separate arts to obtain the result of the device in the current application as neither individual device nor the sum of their parts exhibit the limitation of said expelling material.

Further, the inclusion of the expelling material from the current invention would render the Cohen device inoperable. The expelling material would provide a restive force on the plunger of the Cohen device opposite direction of intention, resulting in either pushing the plunger completely out or moving the plunger a distance proportional to the force of pressure contained in the cylinder.

II. The Graham Factors

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1336-37 (Fed.Cir. 2005). The legal conclusion, that a claim is obvious within § 103(a), depends on at least four underlying factual issues: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations. *Id.*, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

The Scope and Content of the Prior Art

1. Non-Analogous Prior Art

Only references from arts analogous to that of the claimed invention may comprise prior art to the invention. A reference will only be analogous art if: 1) it is from the same field of endeavor as the claimed invention; or 2) it is from a different field of endeavor, but the reference is reasonably pertinent to the particular problem solved by the inventor. *In re Oetiker*, 977 F.2d 1443, 1446-47 (Fed. Cir. 1992); *In re Clay*, 966 F.2d 656, 658-89 (Fed. Cir. 1992). In the *In re Clay* case, the subject claims were directed to a process which improved removal of oil products from storage tanks. The Examiner in that case cited a patent directed to improving production of oil from underground formations. The Federal Circuit held that the cited patent was not analogous art even though the cited patent and subject application both related to the oil industry.

The current reference is not within the field of Applicant's endeavor and not reasonably pertinent to the particular problem with which the inventor was concerned because a person of

ordinary skill, seeking to solve a problem would not reasonably be expected or motivated to look to Cohen in view of Cafiero.

The Cohen device is used to dispense a settable paste during various dentistry operations. One with ordinary skill in the art would not pursue investigation in the dentistry field, in particular a method to deposit a settable paste to temporarily fill a dental cavity, to provide a system of delivery for a precalibrated amount of ingested medication.

The law regarding obviousness is clear--any modification of the prior art must be suggested or motivated by the prior art (or “It is submitted that combining elements from different prior art references (in an attempt to establish obviousness) must be motivated or suggested by the prior art):

‘Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.’ [citation omitted] Although couched in terms of combined teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious “modification” of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.

In re Fitch, 972 F.2d 1260, 23 USPQ2d 1780, 1783-4 (Fed.Cir. 1992), (in part quoting from *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

The Examiner must prove motivation to modify the prior. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”), see also *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998) (“the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”).

This objective evidence must provide motivation to modify the prior art.

We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, although “the suggestion more often comes from the teachings of the pertinent references ...” The

range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. Broad conclusionary statements regarding the teaching of multiple references, standing alone, are not “evidence.”

In re Dembiczaik, 175 F.3d 994, 999 (Fed. Cir. 1999).

The *prima facie case* must be supported by evidence.

“The factual inquiry whether to combine references must be thorough and searching.” It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with:

- Conclusory statements such as those here provided do not fulfill the agency’s obligation
- “Common knowledge and common sense,” even if assumed to derive from the agency’s expertise, do not substitute for authority where the law requires authority.

In re Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

The prior art must show reasonable expectations of success.

“Both the suggestion and the expectation of success must be founded in the prior art, not in applicant’s disclosure.” *In re Dow Chemical Co. v. American Cyanamid Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988).

“Obvious to try or to experiment is not sufficient.” *Yamanouchi Pharmaceutical Co., Ltd. v. Marsam Pharmaceuticals, Inc.*, 231 F.3d 1339, 56 USPQ2d 1641 (Fed. Cir. 2000).

It is submitted that the combination of Cohen and Cafiero is not suggested by the prior art, and even if such a combination were to be made, one would not be led to the combination of features recited in applicant’s claims. In particular, the references do not disclose, teach or suggest the inclusion of an expelling material within the capsule or container used to provide a locomotive aid to the compound stored within the capsule.

It is also submitted that the mere fact that one may argue that the prior art is capable of being modified to achieve a claimed structure does not by itself make the claimed structure obvious--there must be a motivation provided by the prior art, and that motivation is totally lacking in the reference.

The examiner finds the claimed ampule would have been obvious urging that “It would have been obvious to a person with ordinary skill in the art at the time the invention was made to store the device of Cohen in a seal container having a puncturing device built in to reduce the risk of a child accidentally taking an ampule and to provide the user with an easy and convenient puncturing device for the ampule as taught by Cafiero.” Thus, the examiner equates that which is within the capabilities of one skilled in the art with obviousness. Such is not the law. There is nothing in the statutes or case law which makes “that which is within the capabilities of one skilled in the art” synonymous with obviousness.

The examiner provides no reason why, absent the instant disclosure, one of ordinary skill in the art would be motivated to include the binomial compound and plunger actuated deposition device taught from Cohen with the capsule taught from Cafiero, and we can conceive of no reason.

It is further submitted that when a suggestion or motivation to combine selected elements of prior art references is not supplied by the prior art, the incentive to make such a combination can only come from improper hindsight reconstruction using the applicant’s specification.

[T]he Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has stated previously that ‘[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.’ [citations omitted]

In re Fritch, 972 F.2d 1260, 23 USPT2d 1780, 1784 (Fed.Cir. 1992), (in part quoting from *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988)).

To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability. *W.L. Gore & Assoc. v. Garlock, Inc.* 721 F.2d 1132, 1138, 220 USPQ 303, 312-13 (Fed. Cir. 1983). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references “must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention.” *Akzo*

N.V. v. United States Int'l Trade Commission, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986);
Panduit Corp. v. Dennison Mfg. Co., 1 USPQ2d 1593 (Fed. Cir. 1987).

Cohen and Cafiero are complete and functional without the need for modification. Absent the need for modification to provide functionality, the references could never lead one to make modifications to meet the claims.

Conclusion

None of the amendments made herein add new matter.

If the Examiner feels it would advance the application to allowance or final rejection, the Examiner is invited to telephone the undersigned at the number given below.

Reconsideration and allowance of the application as amended is respectfully requested.

DATED this 5th day of December, 2007.

Very respectfully,

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CERTIFICATE OF MAILING

I HEREBY CERTIFY that this correspondence is being electronically deposited with the United States Patent Office via the EFS-Web on the below date as addressed to:

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